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An issued or revision date for these instructions is included for the users information. In the event two years have elapsed between this date and product use, the user should contact Bard Access Systems, Inc. to see if additional product information is available.

Revision date: January, 2007.

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SITE RITE* IV

Ultrasound System



Site~Rite* IV Ultrasound System Operator's Manual

BAIRD


ACCESS SYSTEMS


OPERATOR'S MANUAL

NEXERGY NX1210MU6DBNNZ-001



DO NOT OPEN IN THE PRESENCE
OF FLAMMABLE ANESTHETICS

 120 V~
50 - 60 Hz
Class 2 Power unit

 100 - 250 V
50 - 60 Hz



$\varnothing 14.4V=1.0A$

EGSTON Eggenbug Austria

ATTENTION POUR UTILISATION
L'INTRIEUR SEULEMENT



CAUTION Risk of electric shock
Dry location use only



SN 02C00055


D374657 42560


US Version

NEXERGY NX1210ME6DBNNZ-001



DO NOT OPEN IN THE PRESENCE
OF FLAMMABLE ANESTHETICS

 120 V~
50 - 60 Hz
Class 2 Power unit

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50 - 60 Hz



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ATTENTION POUR UTILISATION
L'INTRIEUR SEULEMENT



CAUTION Risk of electric shock
Dry location use only



SN 02C00055

D374657 42560

EU Version



Do not operate
in the presence
of flammable
anesthetics



Dot Markers
Active



Dot Markers
Inactive



Dangerous
Voltage



Warning : Refer to
Manual Before Use



Refer to Manual
Before Use



Power/
Stand-by



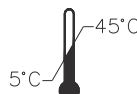
Do Not Dispose
of Battery Pack
In Fire



Medical Electrical Equipment
Classified by UL with respect
to Electrical Shock, Fire, and
Mechanical Hazards only in
accordance with UL 2601-1
and CAN/CSA C22.2 No. 601.1



Humidity
Parameters



Storage
Temperature
Parameters



Temperature
Fault



AC Adapter



Freeze Image



Unfreeze Image

R_X ONLY

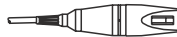
Prescription
Only



Battery Pack



Fragile



Ultrasound
Probe

cm

Depth (In
Centimeters)



Fuse



Decrease
Brightness



Increase
Brightness



Equipotential
Connector



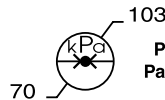
BF Type
Equipment



Reversal



Ground



Pressure
Parameters



0344
European
Conformity



Do Not Open or
Tamper With



Gain



Caution! Hot
Surface



Do not dispose with
ordinary municipal waste

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1 Overview

1.1 Site~Rite[®] IV Ultrasound System

The Site~Rite IV Ultrasound System is an easy to use, lightweight, and portable ultrasound scanner that can be powered either by battery or by A/C power and must be used with *Site~Rite* Ultrasound Probes. The Site~Rite IV Probes are available in frequencies of 7.5 MHz and 9.0 MHz.

For more information about the Site~Rite IV Probes, see Chapter 5, *Site~Rite IV Probes* and Chapter 10, *Technical Specifications*: section 10.2, Site~Rite IV Probes Specifications.

The Site~Rite IV Ultrasound System with associated probes and accessories provide ultrasound imaging of vascular structures, various organs and structures of the body. Ultrasound guidance for placement of needles and catheters in these structures may also be performed. The ultrasound guidance may occur intraoperatively or percutaneously.

The following accessories are available for use with the Site~Rite IV Ultrasound system: Site~Rite Roll Stand, Site~Rite Side Arm, Ultrasound Vessel Phantom, Site~Rite Mini Battery Charger, Charge~Rite Battery Charger, AC Adaptor; Site~Rite Rechargeable Battery Pack, Carrying Case, Sterile Sheaths, Needle Guide Kits (available in 18, 20 and 21 Gauge), and Ultrasound Gel (available in 20 gram Sterile Packets, 60 gram Nonsterile Tubes and 250 ml Nonsterile dispenser.)

1.2 Warnings, Cautions, and Notes

Federal (U.S.A.) law restricts this device to sale by or on the order of physician.
This product should only be operated by qualified medical personnel.

Warnings

- Warning:** This product is regulated by the Federal Food and Drug Administration in the United States of America, as well as other agencies throughout the world. This product is ISO certified and CE approved. Therefore, any modification to the product, except those made by the manufacturer, is strictly prohibited by law.
Federal (U.S.A.) law restricts this device to sale by or on the order of physician.
This product should only be operated by qualified medical personnel.
- Warning:** Do not remove outer protective covers from the Site~Rite IV Scanner. Hazardous voltages exist at several points within the system.
- Warning:** Do not operate the Site~Rite IV Ultrasound System, Charge~Rite Battery Charger or the Site~Rite Mini Battery Charger in the presence of flammable anesthetics or gases. Explosion may result.
- Warning:** Do not use for ophthalmic indications.
- Warning:** Misuse of the Site~Rite IV System may result in damage to the equipment or personal injury.
- Warning:** Use only the Charge~Rite Battery Charger or Site~Rite Mini Battery Charger to charge Site~Rite IV Battery Packs. Use of any other charger to charge Site~Rite IV Battery Packs may damage the battery packs and will void your warranty.
- Warning:** Only connect a Site~Rite IV A/C Adapter to the Site~Rite IV Ultrasound System. Use of any other A/C Adapter may cause intermittent or unpredictable operation, may damage the system and will void your warranty.
- Warning:** Never connect a Site~Rite IV A/C Adapter to the Charge~Rite Battery Charger or Site~Rite Mini Battery Charger.
- Warning:** Never incinerate a battery pack.
- Warning:** Only use the battery packs or A/C adapter to power the scanner.
- Warning:** If a probe is damaged in any way, discontinue use immediately.
- Warning:** Do not subject the probe to mechanical shock. Dropping it or slapping it against an object, such as the palm of the hand, may dislodge sensitive components and cause intermittent or unpredictable operation.
- Warning:** Do not subject the probe to excessive vibration. Vibration may dislodge sensitive components and cause intermittent or unpredictable operation.
- Warning:** Use only **Bard Access Systems** probes with this system; otherwise, patient injury or equipment damage may result.

- Warning:** When using Site-Rite Needle Guides on the fluid standoff probes, use only sterile plastic sheaths that are 1 mil (0.001 inch or 0.0254 mm) thick.
- Warning:** Do not let liquid leak into the scanner, Charge-Rite Battery Charger, Site-Rite Mini Battery Charger, Battery Packs, A/C Adapter, Probe Connector or Probe Port.
- Warning:** Do not attempt to sterilize the Site-Rite IV Scanner or Probes with ethylene oxide or heat sterilization methods. Damage to the devices will result.
- Warning:** Do not soak the probe cable, cable bend reliefs or probe connectors in Cidex solution. Damage to the probe will result.
- Warning:** Never use probes that are out of alignment for needle guidance.
- Warning:** Always properly dispose of dead battery packs. Never incinerate a battery pack. If necessary, return Site-Rite IV Battery Packs to Bard Access Systems, for disposal.
- Warning:** Only qualified personnel should attempt to service this equipment.
- Warning:** The Site-Rite IV System contains dangerous voltages. Service attempts by unqualified personnel may result in serious injury or death.
- Warning:** The Site-Rite IV contains static sensitive components and circuits. Failure to observe proper static control procedures may result in damage to the system.
- Warning:** The following actions void the warranty of the Site-Rite IV System.
- Opening or servicing the scanner or the probe housing.
 - Removal of system labels by anyone other than by Bard Access Systems, authorized service personnel.
 - Opening or servicing the battery pack, A/C adapter, Charge-Rite Battery Charger, or the Site-Rite Mini Battery Charger by anyone other than Bard Access Systems authorized service personnel.
 - Connecting the Site-Rite IV Scanner to any battery source other than the Site-Rite IV Battery Pack.
 - Connecting the Site-Rite IV Battery Packs to any charger other than the Charge-Rite Battery Charger or the Site-Rite Mini Battery Charger.
 - Connecting the Site-Rite IV Scanner to any A/C adapter other than the one provided with the scanner.

Cautions

- Caution:** When using Site-Rite IV Probes in a sterile environment with a Site-Rite Disposable Needle Guide, use only sterile plastic sheaths that are 1 mil (0.001 inch or 0.0254 mm) thick.
- Caution:** Always inspect the ultrasound probe cap, cover and cable before using it with the Site-Rite IV Scanner. Do not use the probe if the cap is cracked or damaged. Do not allow the probe liquid or liquid vapor to contact the eyes, skin, clothing or room furnishings. The fluid can be irritating to the skin and eyes and may damage furniture finishes. In case of contact, immediately rinse the area with water.
- Caution:** Do not scratch the acoustic window (or face) of the probe. Image quality may be degraded if the probe acoustic window (or face) is scratched.
- Caution:** Do not pull the cable to disconnect the probe-connector from the scanner. Pulling the cable may destroy circuit continuity at the connector junction, damage the cable or cable-connector or possibly damage circuit continuity within the scanner.
- Caution:** Do not twist or bend the cable in excess of that required during normal use of the probe. Excessive twisting or bending of the cable may cause failure or intermittent or unpredictable operation.
- Caution:** Do not disinfect the probes using gas or heat methods. Never autoclave a probe.
- Caution:** When disinfecting the probes with Cidex*, do not soak the probe cable, cable bend relief or probe connector in Cidex*. Doing so damages the probe.
- Caution:** Hot water (in excess of 113°F or 45°C) may damage the probe.
- Caution:** Do not expose the probe to direct sunlight for an extended period of time so it does not absorb excessive heat from the sun and damage the probe.
- Caution:** Do not let liquid leak into the Site-Rite IV Scanner, Charge-Rite Battery Charger, Site-Rite Mini Battery Charger, Battery Packs, A/C Adapter, Probe Connector or Probe Port.
- Caution:** Before you connect the A/C adapter to or disconnect the A/C adapter from the Site-Rite IV Scanner, verify that the A/C adapter is not plugged into a wall socket.

- Caution:** Check the alignment of the 7.5 MHz and 9.0 MHz fluid standoff probes at least once a month, or after a probe has experienced any mechanical impact. Do not use a misaligned probe for needle guidance. For the alignment test, see Chapter 5.5, *Periodic Probe Testing*.
- Caution:** Only apply commercially available ultrasonic couplant, which has been specifically formulated for use in medical applications, to the acoustic window (or face) of the probe. Use water or rubbing alcohol and a soft cloth to remove couplant from the acoustic window (or face) of the probe.
- Caution:** Try not to allow ultrasonic couplant to dry on the acoustic window (or face) of the probe. If the couplant should dry, use water or rubbing alcohol and a soft cloth to remove it. Never use a tool of any kind to remove dry couplant from the acoustic window (or face) of the probe.
- Caution:** Some commercially available probe covers contain latex. Natural rubber latex may cause allergic reactions. On March 29, 1991, the U.S. FDA issued an alert titled: "Medical Alert: Allergic Reactions to Latex-Containing Medical Devices." Bard Access Systems distributes sterile kits that do not contain latex.
- Caution:** Do not force the Probe connector. Damage to the connector and system could result.
- Caution:** Use only warm water or rubbing alcohol for Probe cleaning. Use of hot water (temperature exceeding 113°F/45°C) may damage the probe.
- Caution:** During disinfection immerse the probe up to, but not including, the colored cable bend relief.
- Caution:** Always snap the needle guides on to the Probe hook. Do not slide the needle guide on to the needle guide hook, as you may tear the sterile sheath.
- Caution:** Any given Ultrasound Procedure should be performed using the principle of ALARA (As Low As Reasonably Achievable). The Site-Rite IV System holds the acoustic output of the device constant. The licensed medical practitioner should limit the time of patient exposure to ultrasonic radiation using the principle of ALARA.
- Caution:** Only accessories that are approved for use by country and local authorities are to be connected to the Site-Rite IV Scanner. Use of accessories that are not compliant to International Electrical Safety Standards may result in device failure.

Notes

- Note:** If you are using the A/C adapter, the adapter automatically adjusts to the correct line voltage between 100 - 240 VAC, 50 - 60 Hz. The adapter ships with country-specific wall plugs. Verify that the A/C adapter has the appropriate plug for your country's electrical system.
- Note:** The Probe connector can only be inserted in one direction. If the connector does not fit into the probe port, turn the connector over and try again.
- Note:** When in the screens to change the day and time; to discard the changes made to the time and date, press the Freeze Frame button before saving the changes. The date format does not change.
- Note:** When cleaning the system and components, it is important to remove all particles or other matter from all surfaces and crevices.
- Note:** For periodic Probe testing, you may use a deeper intersect guide than 1.5 cm, with the 7.5 MHz probe, or a shallower intersect guide, 0.5 cm or 1.0 cm, with the 9.0 MHz probe.
- Note:** When placing a cold battery in a warm room to charge, the rapid temperature change of the battery occasionally causes the Site-Rite Mini Battery Charger to switch from the Rapid Charge mode to Pending Charge mode (within a few minutes of turning on). If this occurs, remove the Site-Rite Mini Battery Charger from the AC power and remove the battery from the molded battery charger connector; and wait a few moments before reconnecting the Site-Rite Mini Battery Charger to AC power and the battery to the molded battery charger connector.
- Note:** Use of the battery packs in low temperatures reduces battery life.
- Note:** You must follow any local safety requirements when attaching non-Bard Access Systems manufactured accessories.
- Note:** When placing a cold battery in a warm room to charge, the rapid temperature change of the battery occasionally causes the Charge-Rite Battery Charger to switch from the Fast Charge mode to Slow Charge mode prematurely (within a few minutes of turning on). If this occurs, turn Charge-Rite Battery Charger off and wait a few moments before turning Charge-Rite Battery Charger back on.

2 Material Safety Data

2.1 Standoff Probe Fluid

Warning: Contains **n-Butyl Phthalate** (C₁₆H₂₂O₄): Causes eye irritation. May cause skin irritation. Inhalation of high vapor concentrations may be harmful. Avoid contact with eyes, skin and clothing. Avoid breathing vapors. Use with adequate ventilation. Keep container closed. Wash thoroughly after handling. Ingestion of large quantities may cause liver or kidney damage.

Protective Equipment: Wear impervious gloves and eye protection. Provide adequate ventilation.

First Aid

Inhalation – Remove from exposure area to fresh air immediately. If breathing has stopped, give artificial respiration. Keep affected person warm and at rest. Get medical attention.

Skin Contact – Remove contaminated clothing and shoes. Wash affected area with soap or mild detergent and large amounts of water until no evidence of chemical remains (approximately 10 – 20 minutes). Get medical attention if necessary.

Eye Contact – Wash eyes immediately with large amounts of water, occasionally lifting upper and lower lids until no evidence of chemical remains (approximately 15 – 20 minutes). Get medical attention.

Ingestion – If victim is conscious, immediately give 2 to 4 glasses of water and induce vomiting by touching finger to back of throat. Get medical attention immediately.

Supplied To: Bard Access Systems, Inc., Salt Lake City, UT 84116 U.S.A. www.bardaccess.com

Phone: (801) 595-0700

Supplied By: Fisher Scientific, 2000 Park Lane, Pittsburgh, PA 15275 U.S.A.

Phone: (412) 460-8300

3 Setting up the Site~Rite^{*} IV System

Unpack the Site~Rite IV System and verify the contents against the packing slip.

3.1 Assembling the Roll Stand

The roll stand requires some assembly before use.

Assembling the roll stand consists of three tasks:

- Attaching the base to the post.
- Attaching the wire basket.
- Attaching the side arm.

Tools Required

- 3/16 inch Allen wrench
- 1/2 inch open (or box) wrench
- #2 Phillips head screwdriver

Attaching the Base to the Post

To attach the base to the post,

1. Place the base on its side.
2. Slide the post into the center of the base.
3. On the wheel caster side of the base, place the 2" washer over the center of the base. Align the post hole and the washer hole.
4. Use the open wrench to screw the 1/2 inch-long bolt through the washer and into the post.
5. Tighten the bolt.
6. Position the roll stand upright so that it rests on its wheel base.

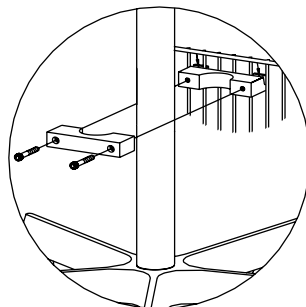
Note: Two of the wheel casters have wheel locking levers that you can flip down to prevent the

roll stand from moving.

Attaching the Wire Basket

To attach the wire basket,

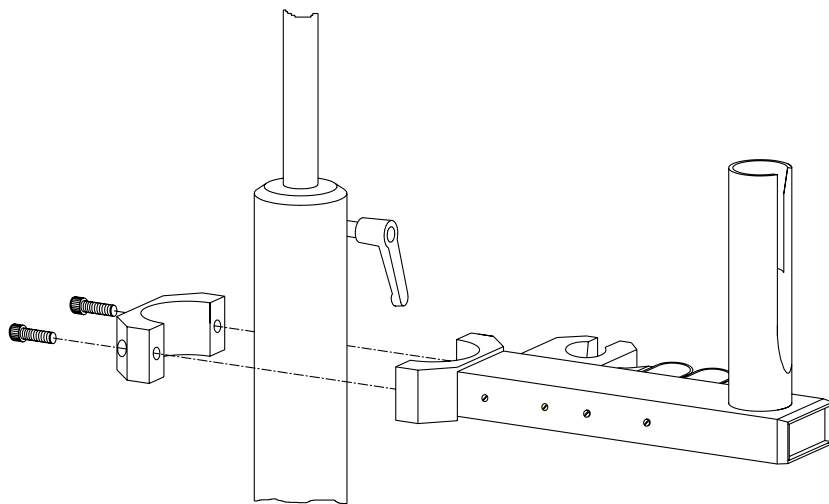
1. Place the basket against the roll stand post, about a third of the way from the top of the post. The open side of the basket faces up.
2. Position the two curved mounting clamps around the post so that the holes in the clamps align with those on the wire basket mounting plate.
3. Use the Phillips head screwdriver to screw the inch-long screws through the mounting clamp holes and into the wire basket mounting plate.
4. Tighten all of the screws. There are two screws per mounting bracket.



Attaching the Side Arm

To attach the side arm,

1. Use the Allen wrench to unscrew the clamp screws.
2. Position and hold the side arm on the roll stand post, just below the adjustment lever (or knob), so that the side arm projects to your right when you face the front of the roll stand. The additional probe and cord holder face toward the back of the roll stand.
3. Position the side arm clamp around the roll stand post, so that the screw holes in both the side arm and the clamp align.
4. Use the Allen wrench to loosely screw both of the Allen screws through the clamp and into the side arm.
5. When the screws are in place, tighten both screws. When you tighten the screws completely,

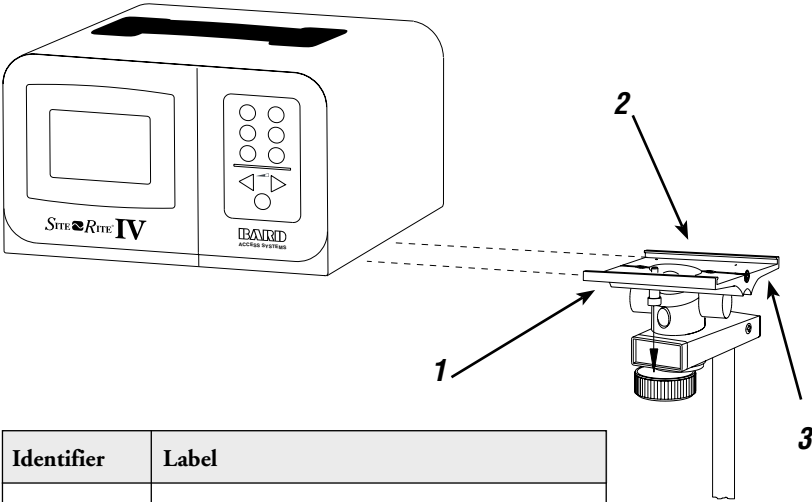


there is a small gap between the side arm and the clamp.

3.2 Attaching the Site~Rite[®] IV Scanner to the Roll Stand

To attach the Site~Rite IV Scanner to the roll stand,

1. Rotate the roll stand so that the locking pin on the mounting plate faces you.
2. Hold the Site~Rite IV Scanner with the front facing you.
3. Position the scanner so that the mounting plate on the underside slides into the grooves on the roll stand's mounting plate.
4. Slide the scanner on to the mounting plate until it touches the locking pin.



Identifier	Label
1	Locking Pin
2	Mounting Plate
3	Stop Screw

5. Pull down on the locking pin, and slide the scanner past the pin. Release the pin when the edge of the scanner mounting plate passes over the locking pin.
6. Continue to slide the scanner, until the locking pin snaps into the locking hole. A stop screw on the opposite side of the mounting plate prevents you from sliding the scanner off of the mounting plate.
7. The Site~Rite IV Scanner is now attached to the roll stand.

If the scanner is temporarily removed from the roll stand, use the scanner by placing it on a horizontal, flat surface. The Site~Rite IV Scanner has four black feet to protect both the bottom of the scanner and the surface on which you place it.

The scanner has a retractable top handle for carrying the scanner when it is temporarily removed from the roll stand.

3.3 Adjusting the Roll Stand Height and Tilt

To adjust the height, unlock the locking mechanism on the roll stand post by turning the locking knob counterclockwise, slide the post up or down, and then lock the mechanism by turning the locking knob clockwise.

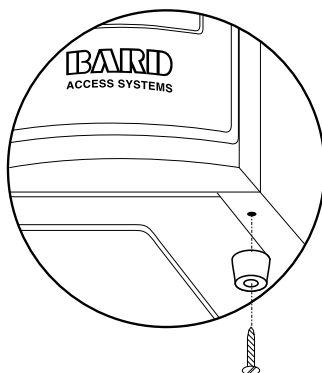
To adjust the tilt, turn the adjustment knob located underneath the Site~Rite IV Scanner, until the desired tilt is achieved.

3.4 Attaching Feet to the Site~Rite[®] IV Scanner (Optional)

The Site~Rite IV Scanner comes with four black rubber feet that can be attached to the bottom of the scanner to allow for tabletop use. The four black rubber feet are included in an individual package with the system.

Since all Site~Rite IV Ultrasound Systems come with a roll-stand the rubber feet are not installed.

The rubber feet can be easily installed on the scanner. Remove the screw in each corner of the scanner. Insert the screw into one of the black rubber feet. Replace the foot and screw back into the corner of the scanner, tightening the screw until secure.



3.5 Attaching Power Sources

The Site~Rite IV System can be powered by either a nickel-metal hydride battery pack or an A/C adapter. Both the battery pack and the A/C adapter attach in the same manner.

For more information about the battery pack, see Chapter 7, *Site~Rite Battery Charger*.

Note: If you are using the A/C adapter, the adapter automatically adjusts to the correct line voltage between 100 - 240 VAC, 50 - 60 Hz. The adapter ships with country-specific wall plugs. Verify that the A/C adapter has the appropriate plug for your country's electrical system.

To connect a power source (battery pack or A/C adapter) to the Site~Rite IV Scanner,

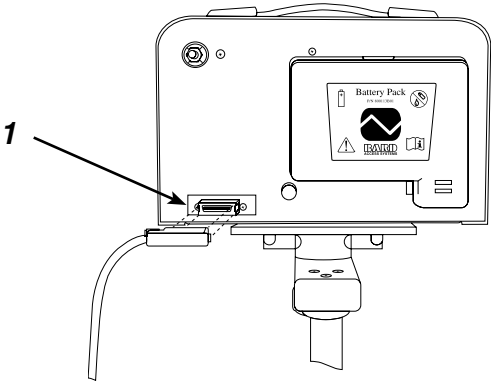
1. Hold the power source so that the power connector projection points down.
2. Align the power source with the scanner's power source connector.
3. Press together the spring clips located on the top and bottom of the power source.
4. Place the power source against the back of the Site~Rite IV Scanner, between the upper and lower guides, and release the clips. The clips snap into the notches on the guides.
5. Gently tug on the power source to verify that it is securely connected to Site~Rite IV Scanner.
6. If you connected an A/C adapter to your Site~Rite IV Scanner, plug the power cord into a wall socket.

To remove a power source from the Site~Rite IV Scanner, press down on the spring clips, and gently pull the power source off of the scanner.

3.6 Connecting and Disconnecting the Probes

To connect a probe,

1. Place the probe into one of the Site~Rite IV Probe holders located on the side arm.
2. Insert the probe connector into the probe port on the rear of Site~Rite IV Scanner. When properly inserted, the connector clicks into place.



Identifier	Label
1	Probe Port

Note: The Probe connector can only be inserted in one direction. If the connector does not fit into the probe port, turn the connector over and try again.

Caution: Do not force the Probe connector. Damage to the connector and system could result.

3. Tug lightly on the connector to verify that the connection is snug.

To disconnect the probe,

1. If the system power is on, power off Site~Rite IV System by pressing the power button on the front of the scanner.
2. Press the sides of the probe connector.
3. Gently pull the connector away from the back of Site~Rite IV Scanner.

For information about probe types and handling, see Chapter 5, *Site~Rite IV Probes*.

For more information about probe specifications, see Chapter 10.2, *Site~Rite IV Probes Specifications*.

3.7 Powering On the Scanner

To power on Site~Rite IV System, do the following:

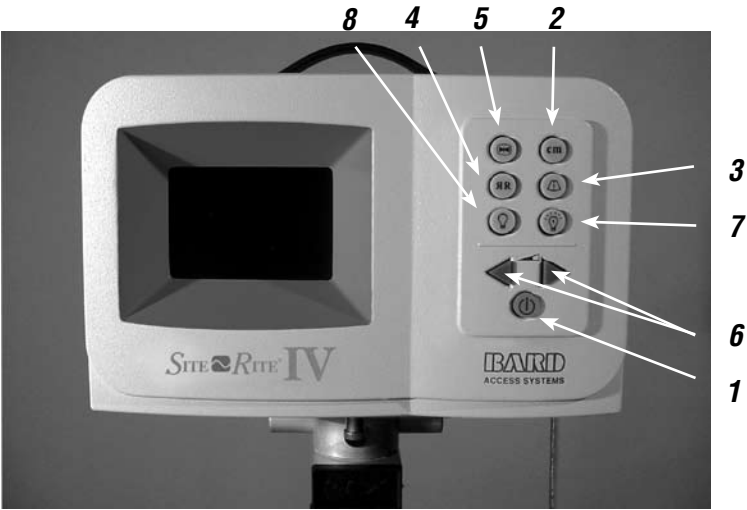
1. Verify that a probe is properly connected to the Site~Rite IV Scanner. A probe must be connected to the scanner for the system to power on.
2. Press the power button located on the front of the Site~Rite IV Scanner.
A green light illuminates inside the power button.
3. Wait approximately 10 seconds for the display screen to illuminate.

To power off the Site~Rite IV System, press the power button again. The system is powered off when the display screen darkens and the green light inside the button turns off.

4 Site~Rite[®] IV Scanner

4.1 Front Panel

The following photograph illustrates the front of the Site~Rite IV Scanner:



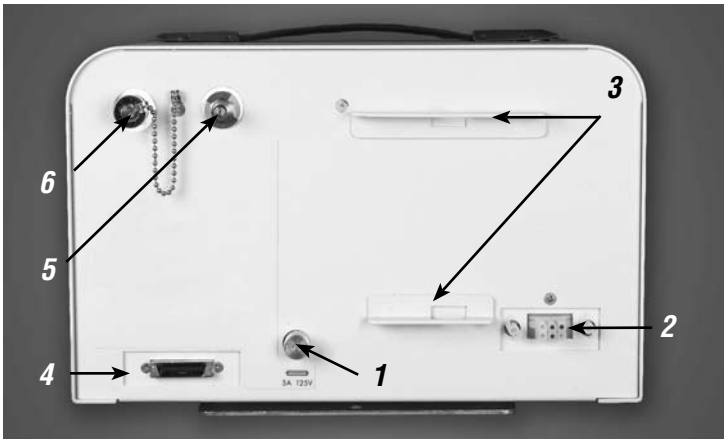
The following table lists and describes the front panel controls and features:

	Controls	Description
1	Power Button	Turns scanner on and off. When on, a light illuminates in the button. Light blinks when 10 minutes of battery power are left.
2	Depth Selection Button	Switches between the different scan depths associated with the type of Site~Rite IV Probe attached to the scanner. The selected depth is highlighted in the upper left-hand corner of the screen; displayed depths are determined by the probe type. For more information about probe scan depths, see Chapter 5, <i>Site~Rite IV Probes</i> .
3	Dot Marker Button	Displays or removes dot markers that overlay the center of the image. Dot markers indicate scan depth from the surface of the skin. By default, dot markers are not displayed. For 9.0 MHz and 7.5 MHz Fluid Standoff Probes —the dots are spaced at intervals of approximately 0.5 cm. Dot markers are not intended for quantitative measurements.
4	Image Reversal Button	Reverses the image from left to right and vice versa. Cannot be used when in Freeze Frame mode. By default, the left edge of the probe displays on the left-hand side of the screen and the “R” icon is highlighted. For orientation information, see Chapter 5.3, <i>Working with the Site~Rite IV Probes</i> .
5	Freeze Frame Button	When pressed, the image on the screen is frozen. Pressing the button a second time returns the scanner to real-time imaging.

	Controls	Description
6	Gain Control Buttons	Controls the gain, or intensity, of the scan image. Reduce gain by pressing on the left-hand side of button. Increase gain by pressing the right-hand side of button. The gain level is displayed as a marker on a horizontal bar at the bottom of the screen, with the least amount of gain on the left-hand side, and greatest amount of gain on the right-hand side. By default, the gain is set to the middle setting.
7	Increase Brightness Button	Controls the brightness of the display. Increase brightness by pressing on the button.
8	Decrease Brightness Button	Controls the brightness of the display. Decrease brightness by pressing on the button.

4.2 Back Panel

The following photograph illustrates the back of the Site~Rite IV Scanner.



The following table lists and describes the back panel features:

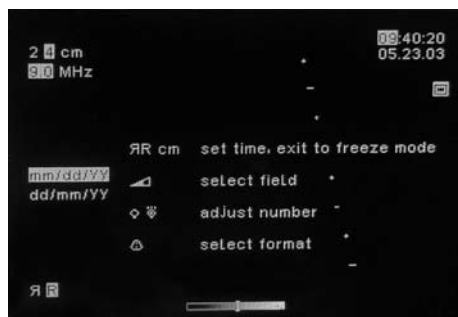
	Feature	Description
1	Fuse	Location of External 5 A 125 V Micro™ Fuse.
2	Power Source Connector	Use the Power Source Connector to connect a battery pack or an A/C adapter to the Site~Rite IV Scanner. See Chapter 3.4, <i>Attaching Power Sources</i> .
3	Battery Brackets	Brackets to which the battery is attached by its clips.
4	Probe Port	Use the probe port to connect a Site~Rite IV Probe to the scanner.
5	Equipotential Connector	Equipotential Ground Connection
6	Video Out	Use the Video Out Port to attach the Site~Rite IV Scanner to external video equipment or printers.

4.3 Setting the Time, Date, and Date Format

The Site~Rite IV Scanner displays the current date and time in the upper right-hand corner of the screen. The time displays in 24-hour format.

To set the current date and time,

1. Press the Freeze button.
The image on the screen freezes.
2. Simultaneously press the Depth Selection and Image Reversal buttons.
New functions display on the screen.
The first number of the time in the upper right-hand corner is highlighted.
3. To change the highlighted number, press the Brightness Increase button to increment the value by one or press the Brightness Decrease button to decrement the value by one.
4. When the highlighted number is correct, press the Gain Increase button to move the cursor to the next value to the right or the Gain Decrease button to move the cursor to the next value to the left.
5. To move the cursor to the desired location, press the Gain Increase or Gain Decrease button repeatedly.
6. Repeat steps 3 - 5 until the desired date and time are set.
7. To change the date format, press the Dot Marker button until the desired date format displays on the left-hand side of the screen. The default date format is mm/dd/yy.
8. To save the changes, simultaneously press the Depth Selection and Image Reversal buttons.
9. Press the Freeze Frame button to return to real-time imaging.



The time, date, and date format settings are saved.

If you entered an invalid time or date, "Invalid Time" or "Invalid Date" displays beneath the time and date, and the scanner remains in edit mode.

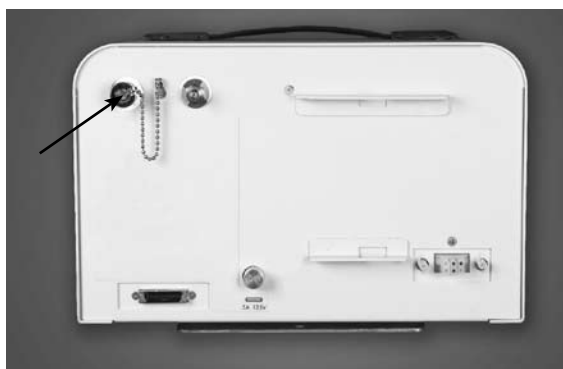
Note: When in the screens to change the day and time; to discard the changes made to the time and date, press the Freeze Frame button before saving the changes. The date format does not change.

4.4 Using the Video Out Feature

On the back of the Site~Rite IV Scanner is a video out port. You can use the video out feature to connect the Site~Rite IV Scanner to third party video equipment, such as a larger monitor.

The video out port is a standard BNC plug. The plug is covered with a twist-off cap to protect it when not in use.

The Site~Rite IV Scanner's video out format is configured to be NTSC compatible.



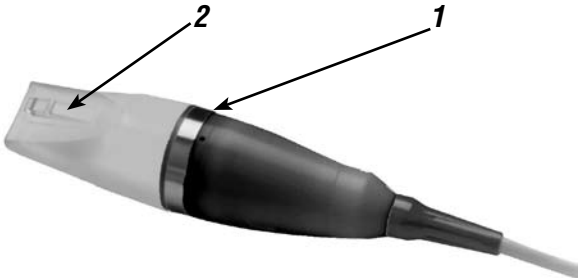
Note: You must follow any local safety requirements when attaching non-Bard Access Systems' manufactured accessories.

Caution: Only accessories that are approved for use by country and local authorities are to be connected to the Site~Rite IV Scanner. Use of accessories that are not compliant to International Electrical Safety Standards may result in device failure.

5 Site~Rite[®] IV Probes

5.1 Overview

Standoff Probe



The following table describes the probe.

	Feature	Description
1	Standoff Probe	Used for superficial imaging to a depth of 4 cm.
2	Needle Guide Hook	Hook to which the short end of the needle guide is clipped.

For superficial imaging, there are two standoff probes:

- 7.5 MHz probe, with a red cable bend relief, optimized for imaging at depths from 1.5 cm to 4 cm below skin surface. The probe images to a depth of 4 cm.
- 9.0 MHz probe, with a blue cable bend relief, optimized for imaging at depths from 0 cm to 1.5 cm below skin surface. The probe images to a depth of 4 cm.

The label on the connector of the probe indicates the probe's frequency, the focal length, and the probe's serial number.

Each probe has two scan depths that you can select using the Site~Rite IV Scanner Depth Selection button.

The following table lists the probe type and bend relief color, scan depths, and scan plane shape:

	7.5 MHz Standoff (Red)	9.0 MHz Standoff (Blue)
Scan Depth Setting*	2 cm	2 cm
	4 cm	4 cm
Image Shape	Trapezoid	Trapezoid

*Default settings are bold.

For more information about Site~Rite IV Scanner functions, see Chapter 4, *Site~Rite IV Scanner*.

How the Probes Work

At the top of each probe is a translucent probe cap, and within the cap is an oscillating transducer. A proprietary fluid surrounds the transducer and fills the cap. While the transducer oscillates an ultrasound beam is emitted that is moved back and forth, creating a wedge-shaped image. At the end of the cap is the acoustic window, through which the ultrasound beam is directed.

The distance between the transducer and the acoustic window defines the shape of the scan plane. The transducer in the standoff probe is located farther from the acoustic window, so the image produced is a truncated sector scan, trapezoidal in shape.

Ultrasound penetrates through fluid and soft tissue, but not through air or bone. Because ultrasound cannot penetrate through air, there must always be a fluid medium between the probe head and the patient's skin to conduct the beam into the patient.

5.2 Handling the Probes

Site~Rite IV Probes are precision instruments and must be handled carefully.

- To hold the probe properly, grasp the probe by the black plastic handle.
- Do not hold the probe by the gray probe cap. The cap is made of a flexible material, and pressing on the sides of the probe cap may restrict the movement of the transducer or damage the probe.
- The probes should never be subjected to heavy vibration or dropped. This may damage the probes or cause misalignment.
- Do not use the probe or the probe cord to move the Site~Rite IV Scanner. Excessive bending or twisting of the probe cord may cause the probe to work intermittently or to fail completely.

5.3 Working with the Site~Rite^{*} IV Probes

Orientation

Standoff Probe (red and blue cable bend relief)

When using a 7.5 MHz probe (red cable bend relief) or 9.0 MHz probe (blue cable bend relief), hold the probe so that the side with the needle guide hook points away from the heart.

Caution: Check the alignment of the 7.5 MHz and 9.0 MHz standoff probes once a month, or after a probe has experienced any mechanical impact. Do not use a misaligned probe for needle guidance. For the alignment test, see Chapter 5.5, *Periodic Probe Testing*.

Warning: If a probe is damaged in any way, discontinue use immediately.

Draping the Probe for Sterile Use

When using Site~Rite IV probe in a sterile environment, the probe and part of the probe cable must be covered with a sterile, acoustically transparent plastic sheath.

Caution: Some commercially available probe covers contain latex. Natural rubber latex may cause allergic reactions. On March 29, 1991, the U.S. FDA issued an alert titled: "Medical Alert: Allergic Reactions to Latex-Containing Medical Devices." Bard Access Systems, Dymax Corporation distributed sterile kits do not contain latex.

To drape the probe for sterile use,

1. Place the probe in the side arm probe holder on the roll stand.
2. Apply a layer of non-sterile ultrasonic coupling gel on the acoustic window of the probe head.
3. Make sure that the sheath is fully rolled up.
4. Place the sheath over the probe head, being careful not to wipe off the coupling gel.
5. Cover the probe and cable with the sheath.
6. Smooth the sheath over the acoustic window of the probe head to remove any air bubbles or folds in the sheath.
7. Use the poly-bands to hold the sheath in place.
8. Apply a layer of sterile coupling gel to the sheathed acoustic window. Sterile gel is included in the Site~Rite IV Sterile Kit.

Warning: When using Site~Rite Needle Guides on the fluid standoff probes, use only sterile plastic sheaths that are 1 mil (0.001 inch or 0.0254 mm) thick.

5.4 *Cleaning and Disinfecting the Scanner and Probes*

Warning: Do not attempt to sterilize the Site~Rite IV Scanner or Probes with ethylene oxide or heat sterilization methods. Damage to the devices will result.

Recommendations for Cleaning the Site~Rite IV Scanner

To clean the scanner:

1. Dampen a nonabrasive cloth with either warm water or rubbing alcohol.
2. Gently wipe the dampened cloth over the areas of the scanner requiring cleaning.

Note: When cleaning the system and components, it is important to remove all particles or other matter from all surfaces and crevices.

Warning: Do not let liquid leak into the scanner, Charge~Rite Battery Charger, Site~Rite Mini Battery Charger, Battery Packs, A/C Adapter, Probe Connector, or Probe Port.

Recommendations for Cleaning the Charge~Rite Battery Charger and Site~Rite Mini Battery Charger

To clean the battery charger:

1. Dampen a nonabrasive cloth with either warm water or rubbing alcohol.
2. Gently wipe the dampened cloth over the areas of the battery charger requiring cleaning.

Note: It is important to remove all particles or other matter from all surfaces and crevices.

Warning: Do not let liquid leak into the scanner, Charge~Rite Battery Charger, Site~Rite Mini Battery Charger, Battery Packs, A/C Adapter, Probe Connector, or Probe Port.

Recommendations for Cleaning the Site~Rite Roll Stand

To clean the roll stand:

1. Dampen a nonabrasive cloth with either warm water or rubbing alcohol.
2. Gently wipe the dampened cloth over the areas of the roll stand requiring cleaning.

Note: It is important to remove all particles or other matter from all surfaces and crevices.

Recommendations for Cleaning the Site~Rite IV Probes

The probes should be cleaned and disinfected after each use.

To clean the probes:

1. Dampen a nonabrasive cloth with either warm water or rubbing alcohol.
2. Gently wipe the dampened cloth over the probe head and handle.

Note: It is important to remove all particles of adhering tissue, ultrasound gel, dried blood, or other matter from all surfaces and crevices.

Note: Immediately after cleaning, the probes should be rinsed thoroughly with warm water or rubbing alcohol.

Caution: Use only warm water or rubbing alcohol for Probe cleaning. Use of hot water (temperature exceeding 113°F/45°C) may damage the probe.

Warning: Do not let liquid leak into the scanner, Charge~Rite Battery Charger, Site~Rite Mini Battery Charger, Battery Packs, A/C Adapter, Probe Connector, or Probe Port.

Recommendations for Liquid Disinfection of the Site~Rite IV Probes

The Site~Rite IV Probes may be liquid disinfected by soaking them in Cidex^{*} plus 28 day solution available from Johnson and Johnson Medical, Inc.

Follow the solution manufacturer's recommendations for soak time necessary to achieve the desired germicide level of activity.

Caution: During disinfection immerse the probe up to, but not including, the colored cable bend relief.

Warning: Do not soak the probe cable, cable bend reliefs, or probe connectors in Cidex solution. Damage to the probe will result.

Warning: Do not let liquid leak into the scanner, Charge~Rite Battery Charger, Site~Rite Mini Battery Charger, Battery Packs, A/C Adapter, Probe Connector, or Probe Port.

The germicide level of activity selected should be consistent with the degree of risk of infection involved in the use of the device.

Risk Classification	Patient Applications	Minimum Germicide Level of Activity Recommendation*
Non-critical	Probe used in contact with intact skin only, e.g. abdominal or peripheral vascular imaging.	Clean and low-level disinfect between uses.
Semi-critical	Probe used in contact with mucous membranes, e.g. transvaginal imaging.	Clean, high-level disinfect. Use a probe sheath during application.
Critical	Probe used in contact with blood, compromised tissue, or in a sterile field, e.g. intraoperative imaging, biopsy procedures.	Clean, high-level disinfect or sterilize. <u>Use a sterile probe sheath during application.</u>

*Refer to the solution manufacturer’s instruction on the soak time necessary to achieve these germicide levels of activity.

Warning: Do not attempt to sterilize the Site-Rite IV Scanner or Probes with ethylene oxide or heat sterilization methods. Damage to the devices will result.

5.5 Periodic Probe Testing

The 7.5 MHz (red cable bend relief) and 9.0 MHz (blue cable bend relief) standoff probes should be tested for proper alignment on a monthly basis, or when the probe has been dropped or mistreated.

Warning: Never use probes that are out of alignment for needle guidance.

Warning: If a probe is damaged in any way, discontinue use immediately.

In addition to the scanner and probe, the following items are required:

- Site-Rite Disposable Needle Guide.
- Needle that fits the needle guide.
- Container of clear water at least 8 cm deep.

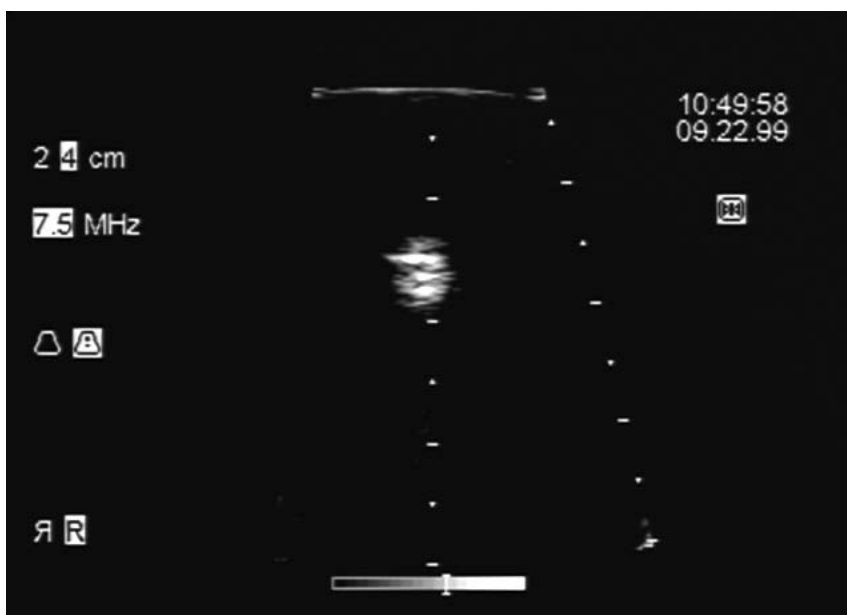
To check the probe for proper alignment,

1. Connect the probe to the Site-Rite IV Scanner.
2. Press the Power button.
3. Press the Dot Marker button to display the center dot markers on the screen.
4. Clip 1.5 cm Site-Rite Disposable Needle Guide on to the probe, and insert the appropriate needle into the guide, bevel facing away from the probe.

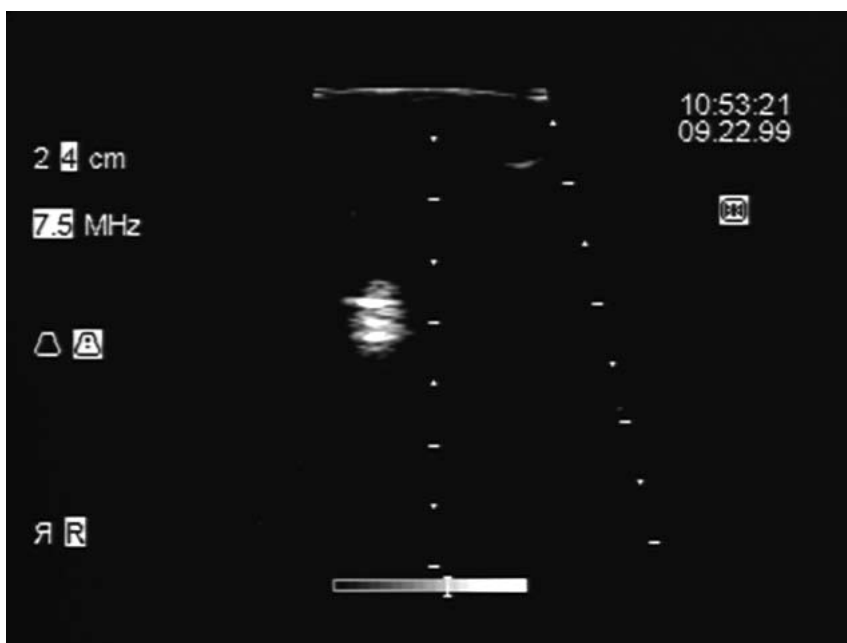
Note: For periodic Probe testing, you may use a deeper intersect guide than 1.5 cm, with the 7.5 MHz probe, or a shallower intersect guide, 0.5 cm or 1.0 cm, with the 9.0 MHz probe.

5. Immerse the tip of the probe in a container of clear water.
6. Advance the needle until the tip displays as a bright dot on the Site-Rite IV Screen.

- If the needle aligns with the center dot markers—the probe is aligned properly.



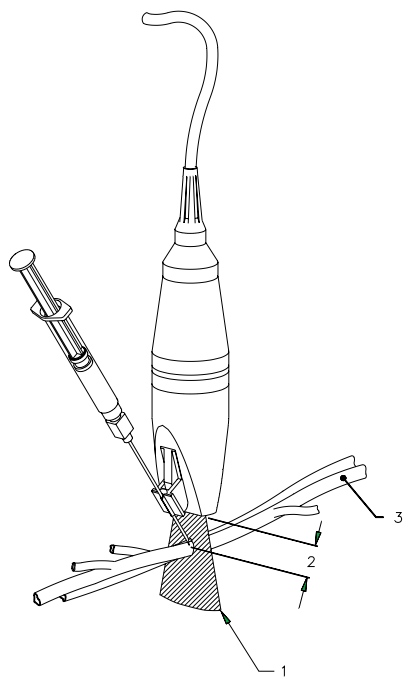
- If the needle displays to either side of the dot markers—the probe is misaligned and must be returned to Bard Access Systems for repair. For information about returning items to Bard Access Systems for repair, see Chapter 9.2, *Service*.



6 Site~Rite[®] IV Needle Guides

The 7.5 MHz (red cable bend relief) and 9.0 MHz (blue cable bend relief) fluid standoff probes are designed to be used with the Site~Rite Disposable Needle Guides and have a needle guide hook on one of the broad sides of the probe.

The Site~Rite Needle Guides direct a needle so that it will cross the ultrasound beam at a predetermined depth that lies along the path of the dot markers.



The following table describes the needle guides.

	Feature	Description
1	Ultrasound Plane	The plane that is viewed on the scanner display.
2	Intersection Depth	Needle guides allow for needle depth location within the ultrasound plane from 0.5 cm to 3.5 cm.
3	Jugular Vein	Within the illustration the Jugular Vein and Carotid Artery are depicted.

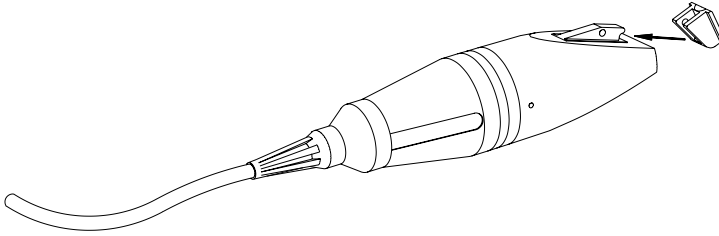
6.1 Attaching the Needle Guide to the Probe

To attach the needle guide to a probe,

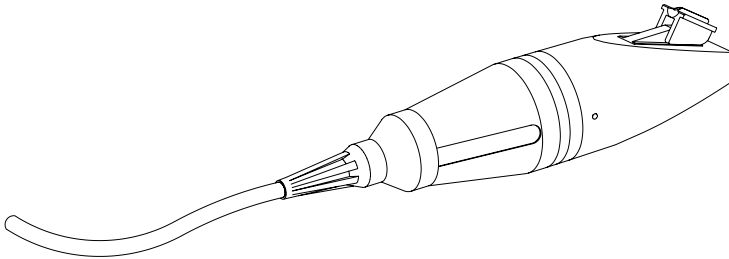
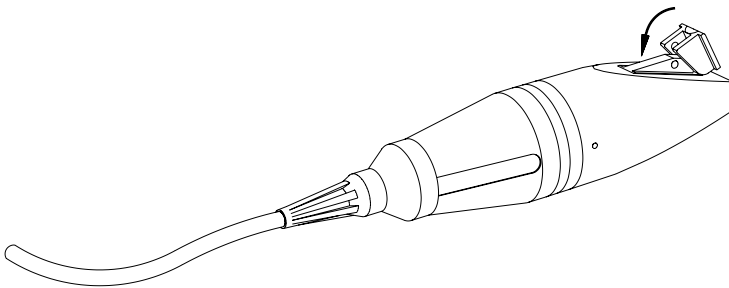
1. Choose the appropriate needle guide based on the depth of the structure to be punctured and the gauge of the needle to be used.

Note: Needle guides can only be used over a sterile Site~Rite Probe sheath in order to maintain sterility of the Site~Rite IV Probe. For information about sterile draping, see Chapter 5.3, *Working with the Site~Rite IV Probes*.

2. Clip the short end of the needle guide to the end of the needle guide hook closest to the top of the probe.



3. Push the larger end of the needle guide toward the probe until the needle guide snaps on to the needle guide hook. Do not slide.

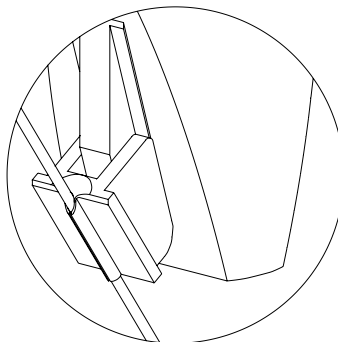


Caution: Always snap the needle guides on to the Probe hook. Do not slide the needle guide on to the needle guide hook, as you may tear the sterile sheath.

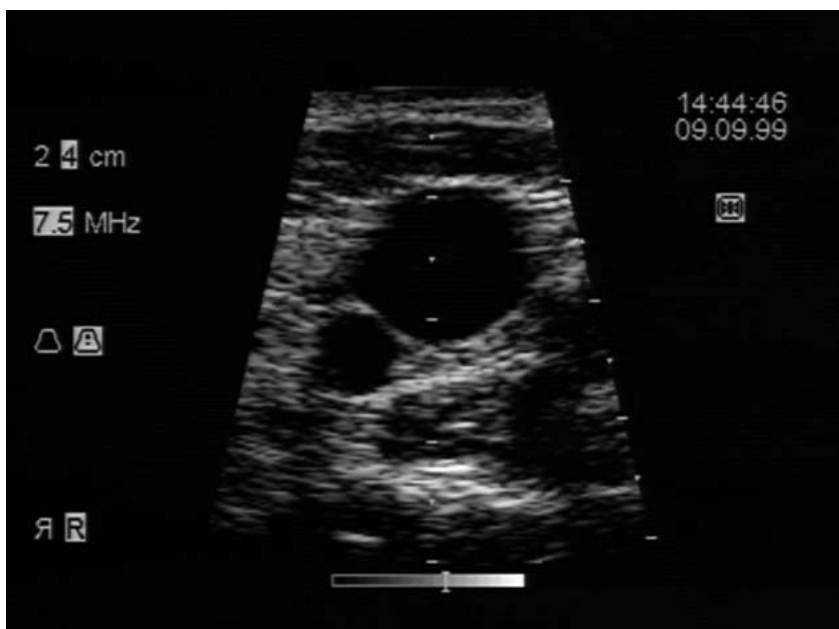
6.2 Using the Needle Guides

To use the needle guide,

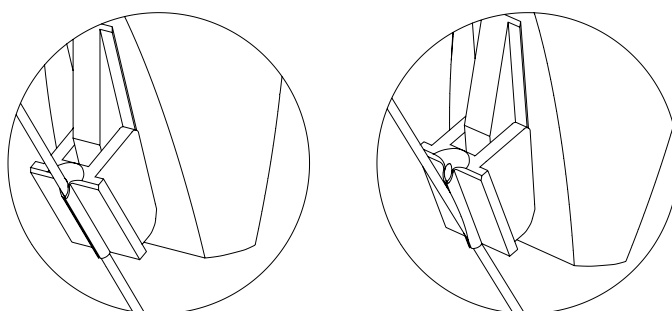
1. Slide the appropriately sized needle, beveled edge facing the probe, into the channel on the guide.



2. Place the probe against the skin, perpendicular to the target vessel. Hold the probe so that the needle guide points away from the heart.
3. Center the dot markers on the target vessel.

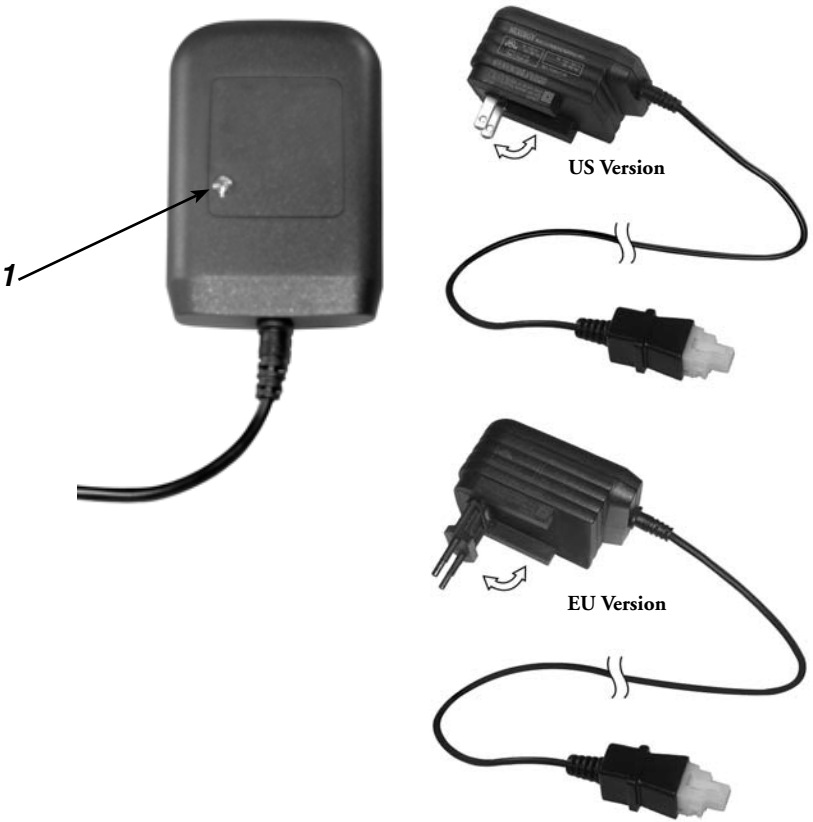


4. While keeping the dot markers centered on the target vessel, slowly advance the needle while looking at the screen of the Site~Rite IV scanner. When the needle approaches the target vessel, you should see the anterior wall indenting. Once puncture occurs, the vessel returns to normal shape.
5. Hold the needle, then gently rock the probe away from the needle for a smooth separation. The needle guide channel opens, and the needle smoothly disengages from the guide.



7 Site~Rite[®] IV Battery Charger

7.1 Site~Rite[®] Mini Battery Charger



The following table lists and describes the indicator light features:

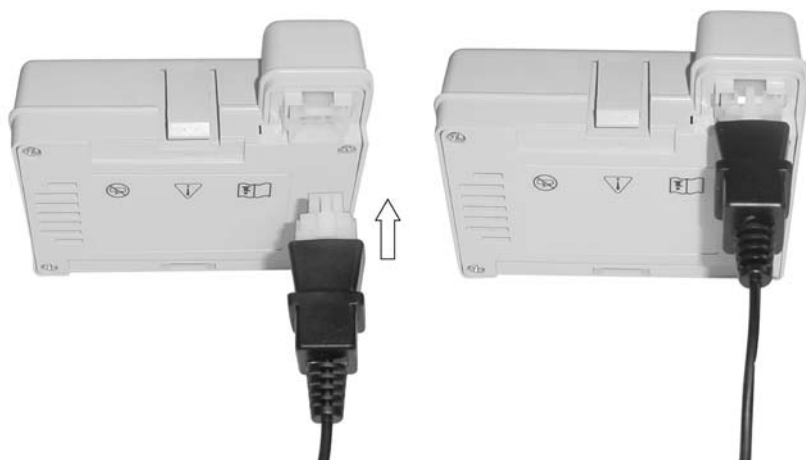
	Feature	Description
1	Rapid Charge	Battery Charger LED indicator Flashes Green
	Charge Complete	Battery Charger LED indicator Continuous Green Color
	Charge Pending	Battery Charger LED indicator Continuous Amber Color
	Charge Failure	Battery Charger LED indicator Flashes Amber Color
	No AC or No Battery	Battery Charger LED indicator OFF

The Site~Rite Mini battery charger is used to charge Site~Rite IV Battery Packs. The battery charger is plugged into any standard power outlet and automatically adjusts to run on any line voltage between 100 - 250 VAC, 50 - 60 Hz. Each battery charger is shipped with a country-specific wall plug. Be sure that the battery charger has the appropriate plug for your country's electrical system.

The Site~Rite Mini Battery Charger does not have an external fuse.

Warning: Use only the Site~Rite Mini Battery Charger or Charge~Rite Battery Charger to charge Site~Rite IV Battery Packs. Use of any other charger to charge Site~Rite IV Battery Packs may damage the battery packs and will void your warranty. Never connect a Charge~Rite Battery Charger or Site~Rite IV A/C Adapter to a Site~Rite Mini Battery Charger.

7.2 Charging the Battery with the Site~Rite[®] Mini Battery



Charger

Site~Rite IV Battery Packs are fully charged prior to shipment, but may require charging before use.

To charge a battery pack with the Site~Rite Mini Battery Charger,

1. Plug the Site~Rite Mini Battery Charger into a power outlet.
2. Verify that the LED indicator on the front of the Site~Rite Mini Battery Charger is not illuminated.
3. Attach the battery pack to the Site~Rite Mini Battery Charger. The battery packs attach to the Site~Rite Mini Battery Charger by inserting the molded battery charger connector into the matching connector of the battery pack.
 - Hold the battery pack with the plug port visible.
 - Place the molded battery connector of the Site~Rite Mini Battery Charger into the plug port.
 - The molded battery connector will lock into the battery pack port.
 - Gently tug on the pack to verify that it is securely connected to the Site~Rite Mini Battery Charger.
4. The LED indicator will flash green to indicate that the charger is in Rapid Charge.

After approximately 3 hours, the LED indicator will glow solid green to indicate charge complete.

Following Rapid Charge the battery charger will continue to provide a trickle/top-off charge for 4 hours. The battery charger will then provide maintenance charge to the battery for a 10 hour period.

Note: When placing a cold battery in a warm room to charge, the rapid temperature change of the battery occasionally causes the Site~Rite Mini Battery Charger to switch from the Rapid Charge mode to Pending Charge mode (within a few minutes of turning on). If this occurs, remove the Site~Rite Mini Battery Charger from the AC power and remove the battery from the molder battery charger connector; and wait a few moments before reconnecting the Site~Rite Mini Battery Charger to AC power and the battery to the molded battery charger connector.

To remove a battery pack from Site~Rite Mini Battery Charger,

1. Press down on the molder battery charger connector spring lock, and gently pull the battery pack off of the connector.

You can remove the Site~Rite Mini Battery Charger from AC power and remove the battery for use when the Rapid Charge indicator glows solid green. At the end of the Rapid Charge cycle, the battery is approximately 85% charged. The Site~Rite Mini Battery Charger then switches to the Pending Charge mode to continue the charging process while preventing the battery from overheating. Using a partially charged battery does not create battery memory or reduce the life of the battery.

No harm occurs if you leave the battery on the Site~Rite Mini Battery Charger after it is fully charged.

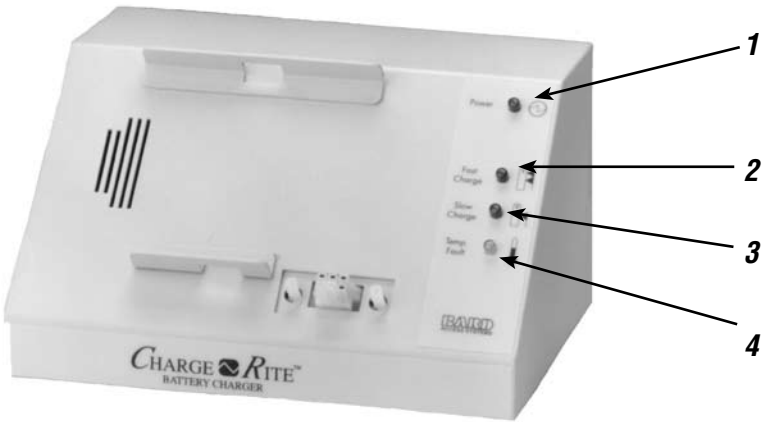
7.3 Charge~Rite[™] Battery Charger

The Charge~Rite Battery Charger is used to charge Site~Rite IV Battery Packs. The Charge~Rite Battery Charger plugs into a standard power outlet and automatically adjusts to run on any line voltage between 90 - 264 VAC, 47 - 63 Hz. The Charge~Rite Battery Charger is shipped with country-specific wall plugs. Be sure that the Charge~Rite Battery Charger has the appropriate plug for your country's electrical system.

Charge~Rite fuses are located next to the power switch on the back of the unit. Use only F250 V/3.0A fuses in the unit.

Warning: Use only the Charge~Rite Battery Charger or Site~Rite Mini Battery Charger to charge Site~Rite IV Battery Packs. Use of any other charger to charge Site~Rite IV Battery Packs may damage the battery packs and will void your warranty. Never connect a Site~Rite IV A/C Adapter to a Charge~Rite Battery Charger or Site~Rite Mini Battery Charger.

7.4 Indicator Lights



The following table lists and describes the indicator light features:

	Feature	Description
1	Power	Charge~Rite Battery Charger is powered on.
2	Fast Charge	Battery is charging in Fast Charge mode.
3	Slow Charge	Battery is charging in Slow Charge or Maintenance mode.
4	Temperature Fault	<p>Battery is either too hot or too cold to charge.</p> <p>If Temperature Fault and Power indicators illuminate—the battery is too hot. Turn the Charge~Rite Battery Charger off and wait several minutes for the battery to cool down.</p> <p>If Temperature Fault and Slow Charge indicators illuminate—the battery is too cold. The Charge~Rite Battery Charger charges the battery in Slow Charge mode until the battery is warmed up.</p> <p>When the battery is at normal temperature, the Temperature Fault and Slow Charge lights turn off and the Charge~Rite Battery Charger automatically switches to the Fast Charge mode, illuminating the Fast Charge light. Charging continues normally.</p>

7.5 Charging the Battery with the Charge~RiteTM Battery Charger

Site~Rite IV Battery Packs are fully charged prior to shipment, but may require charging before use.

To charge a battery pack with the Charge~Rite Battery Charger,

1. Plug the Charge~Rite Power Cord into a power outlet.
2. Verify that the power switch on the back of the Charge~Rite Battery Charger is switched to Off and that the Power indicator on the front of the Charge~Rite Battery Charger is not illuminated.
3. Attach the battery pack to the Charge~Rite Battery Charger. The battery packs attach to the Charge~Rite Battery Charger in the same manner as they attach to the Site~Rite 3 Scanner:
 - Hold the battery pack with the plug port pointing down, and press together the spring clips located on the top and bottom of the pack.
 - Place the battery pack against the front of the Charge~Rite Battery Charger, between the upper and lower guides, and release the clips. The clips snap into the notches on the guides.
 - Gently tug on the pack to verify that it is securely connected to the Charge~Rite Battery Charger.
4. On the back of the Charge~Rite Battery Charger, turn the power switch to On. On the front of the Charge~Rite Battery Charger, the Power indicator and the Fast Charge indicator illuminate to indicate that the charger is in Fast Charge mode.

After approximately 2 hours, the Fast Charge indicator turns off and the Slow Charge indicator illuminates. Slow Charge lasts for approximately 2 hours.

The total charging cycle (both slow and fast charge) lasts approximately 5 hours, after which the battery is fully charged.

Note: When placing a cold battery in a warm room to charge, the rapid temperature change of the battery occasionally causes the Charge~Rite Battery Charger to switch from the Fast Charge mode to Slow Charge mode prematurely (within a few minutes of turning on). If this occurs, turn Charge~Rite Battery Charger off and wait a few moments before turning Charge~Rite Battery Charger back on.

To remove a battery pack from Charge~Rite Battery Charger,

1. On the back of Charge~Rite Battery Charger, turn the power switch to Off, and verify that the Power indicator on the front of Charge~Rite Battery Charger is not illuminated.
2. Press down on the battery pack's spring clips, and gently pull the pack off of Charge~Rite Battery Charger.

You can turn off Charge~Rite Battery Charger and remove the battery for use when the Fast Charge indicator turns off. At the end of the Fast Charge cycle, the battery is approximately 85% charged. Charge~Rite Battery Charger then switches to the Slow Charge mode to continue the charging process while preventing the battery from overheating. Using a partially charged battery does not create battery memory or reduce the life of the battery.

No harm occurs if you leave the battery on Charge~Rite Battery Charger after it is fully charged. Charge~Rite Battery Charger enters into a maintenance charge cycle to maintain the battery at full charge.

7.6 Battery Life

A fully charged battery pack has a minimum operating life of two hours.

Nickel Metal Hydride batteries slowly discharge when not in use. Higher temperatures cause batteries to self-discharge faster.

Nickel Metal Hydride batteries are classified by the United States Federal government as a non-hazardous waste and are safe for disposal in the normal municipal waste stream. *Exception: California, which requires non-households to dispose of these batteries in accordance with the California Universal Waste Rules.*

Nickel Metal Hydride batteries do contain recyclable materials and are accepted for recycling by the Rechargeable Battery Recycling Corporation's (RBRC) Battery Recycling Program. In the United States please call 1-800-8-BATTERY for information on recycling used Nickel Metal Hydride batteries.

Outside of the United States dispose of batteries in accordance with local regulatory requirements.

Note: Use of the battery packs in low temperatures reduces battery life.

Warning: Always properly dispose of dead battery packs in accordance with local regulations. Improper disposal may present an environmental hazard.

8 Site~Rite^{*} IV System Maintenance and Troubleshooting

8.1 Operating and Storage Conditions

The Site~Rite IV System should not be operated or stored in conditions beyond the following tolerances:

Condition	Tolerance
Operating Temperature:	59°F to 100°F (15°C to 38°C)
Storage Temperature:	41°F to 113°F (5°C to 45°C)
Operating and Storage Humidity:	5% to 95% Relative Humidity (non-condensing)
Operating and Storage Atmospheric Pressure:	-500 feet to 10,000 feet elevation (103 kPA to 70 kPA)

8.2 Troubleshooting

If you have problems with the operation of your Site~Rite IV System, review this section before contacting Bard Access Systems.

Common Problems and Solutions

The following table describes common problems, possible causes, and suggested solutions:

Problem	Possible Cause	Solution
Scanner does not turn on.	Battery pack is depleted.	Remove battery pack and replace with a fully charged battery pack.
	Battery pack or A/C adaptor not properly connected to scanner.	Verify that power source is firmly connected to back of scanner.
	Probe not properly connected or not connected at all.	Verify that probe is properly connected to scanner.
	Probe damaged.	Attach different Site~Rite IV Probe and power on. If scanner functions, return probe for repair. If scanner does not function, return scanner for repair.
	A/C adaptor is not properly attached to an outlet.	Verify that the A/C adaptor is properly attached to a functional outlet.
	The Battery Pack is defective.	Replace the Battery Pack.

Problem	Possible Cause	Solution
Scanner turns on for a moment, then shuts off.	Battery pack is depleted.	Remove battery pack and replace with a fully charged battery pack.
Scanner halts, stutters, then restarts.	Operator may be applying too much pressure on the probe cap, thereby affecting operation of the internal bearings.	Do not press on the sides of the probe cap. Hold probe by the handle.
Scanner turns on, screen lights up, but no image displays.	Probe is too cold.	Wait for probe to warm up.
	Probe is damaged.	Return probe for repair.
	The Probe Assembly is not connected or connected improperly.	Properly connect the Probe Assembly.
Scanner turns on, display is normal shaped, and the internal Probe Assembly does not oscillate.	The Probe Assembly is defective.	Replace the Probe Assembly with a known functioning assembly. Return the probe for repair.
Scanner turns on, screen lights up, text is displayed but no image displays and a Sync Timeout error message is displayed on the screen.	The Probe Assembly is not connected or connected improperly.	Properly connect the Probe Assembly.
	The Probe Assembly is defective.	Replace the Probe Assembly with a known functioning assembly. Return the probe for repair.
Battery pack does not remain attached to scanner.	Clips on battery pack are not in the bracket holes on the back of scanner.	Reconnect battery pack.
	Battery pack is broken.	Return battery pack for repair.
Artifacts display throughout image.	Nearby electrical interference.	Change location of scanner, or turn off interfering device.
System functions normally, but the display wobbles or flickers.	The Probe Assembly is located too close to the monitor.	Relocate the Probe Assembly.
Poor or incomplete image displayed.	Inadequate acoustic coupling between probe and sterile sheath or probe and skin.	Add more acoustic gel between probe and sterile sheath or probe and skin.
	Fold or seam overlays the acoustic window of probe.	Smooth out sheath over acoustic window.

Problem	Possible Cause	Solution
Probe makes knocking sound.	Probe is damaged.	Return probe for repair.
System functions normally, but the Gain Control is not functioning	System is in the Freeze Mode.	Press the Freeze Button.
Probe has bubbles.	Probe is damaged.	Return probe for repair.
Image quality is poor or ultrasound beam inadequately penetrates.	Insufficient quantity of acoustic coupling gel used.	Add additional acoustic coupling gel.
During normal operation the scanner shuts down without warning.	The low battery detection circuits are defective.	Remove battery pack and replace with fully charged battery pack. Return scanner for repair.

Error Messages

The Site~Rite IV Scanner displays error messages when certain conditions exist. The following table describes the error messages and actions to take to correct the error.

Problem	Possible Cause
Invalid Probe No Probe Invalid Depth	The system cannot identify the probe attached to the scanner. Turn scanner off. Verify that probe is connected correctly, and then power scanner on. If message repeats, call Bard Access Systems, (in US) or local distributor (outside of US).
Probe over power error	The probe attached to the scanner is not oscillating correctly. Turn scanner off. If probe is cold, warm probe to room temperature by immersing the cap in a cup of warm water. Verify that the probe is connected correctly, and then power scanner on. If message repeats, call Bard Access Systems (in US) or local distributor (outside of US).
LCD thermal shutdown imminent	Turn scanner off. Allow system to return to room temperature and then power system on. If message repeats, call Bard Access Systems (in US) or local distributor (outside of US).
CRC error	The software running the system is damaged. Call Bard Access Systems (in US) or local distributor (outside of US).
Watchdog time out	The system hardware or software has failed. Call Bard Access Systems (in US) or local distributor (outside of US).
Sync timeout	Turn scanner off. If probe is cold, warm probe to room temperature by immersing the cap in a cup of warm water. Verify that the probe is connected correctly, and then power scanner on. If message repeats, call Bard Access Systems, (in US) or local distributor (outside of US).
Other Error Messages	Call Bard Access Systems (in US) or local distributor (outside of US).

9 Warranty and Service

9.1 Coverage

The manufacturer, Bard Access Systems, warrants this product against defects in material or workmanship for a period of one year from the date of original purchase, and agrees to repair, or at Bard Access Systems' discretion, replace any defective unit free of charge. The warranty on the repaired or replaced unit continues from the purchase date of the original unit.

This warranty does not cover damages resulting from misuse, abuse, modification, or alteration of the Site-Rite IV System.

The following actions void the warranty of the Site-Rite IV System.

- Opening or servicing the scanner or the probe housing.
- Removal of system labels by anyone other than by Bard Access Systems authorized service personnel.
- Opening or servicing the battery pack, A/C adapter, Charge-Rite Battery Charger or the Site-Rite Mini Battery Charger by anyone other than Bard Access Systems, Dymax Corporation authorized service personnel.
- Connecting the Site-Rite IV Scanner to any battery source other than the Site-Rite IV Battery Pack.
- Connecting the Site-Rite IV Battery Packs to any charger other than the Charge-Rite Battery Charger or Site-Rite Mini Battery Charger.
- Connecting the Site-Rite IV Scanner to any A/C adapter other than the one provided with the scanner.

THIS LIMITED PRODUCT WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED (INCLUDING, WITHOUT LIMITATION ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE).

THE LIABILITY AND REMEDY STATED IN THIS LIMITED PRODUCT WARRANTY WILL BE THE SOLE LIABILITY OF BARD ACCESS SYSTEMS AND REMEDY AVAILABLE TO PURCHASER FOR THIS PRODUCT, WHETHER IN CONTRACT, TORT (INCLUDING NEGLIGENCE) OR OTHERWISE, AND BARD ACCESS SYSTEMS WILL NOT BE LIABLE TO PURCHASERS FOR ANY SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES ARISING OUT OF ITS HANDLING OR USE.

9.2 Service

Warning: Only qualified personnel should attempt to service this equipment.

Warning: The Site-Rite IV System contains dangerous voltages. Service attempts by unqualified personnel may result in serious injury or death.

Warning: The Site-Rite IV System contains static sensitive components and circuits. Failure to observe proper static control procedures may result in damage to the system.

If you have performance problems with the Site-Rite IV System, first consult Chapter 8.2, *Troubleshooting*. If you cannot solve the problem through troubleshooting, your system may require repair. Before returning any item for repair, contact:

In the United States—Bard Access Systems at (801)-595-0700, (800)-545-0890.

Outside of the United States—your local distributor, Bard Access Systems +1 801 595 0700.

Authorized European Service Representative

Bard Limited
Forest House, Brighton Road
Crawley, West Sussex RH11 9BP
England
Phone: + 44 1293 527888
FAX: + 44 1293 528454

10 Technical Specifications

10.1 Site~Rite* IV Scanner Specifications

Dimensions: 10" x 6.75" x 8" (540 in³)

Weight: 6.2 lbs. (2.8 kg)

Power Sources: AC adapter, DC Battery Pack

Power Consumption: 14.4 VDC @ 1.5 A

Monitor Size: 3.8"

Y2K Compliant: yes

IEC 60601- 1: Class I, Type BF Applied Part, Continuous Operation, Internally Powered Equipment, Not Category AP or APG Equipment, Not protected against ingress of water.

Probes: 7.5 MHz, 9.0 MHz

Fuse: 5 A 125 V MicroTM Fuse (Part Number: 273 005 Manufactured by Littelfuse, Inc.)

10.2 Site~Rite* IV Probe Specifications

9.0 MHz Probe

Ultrasonic Frequency: 9.0 MHz

Sector Angle: 26°

Crystal to Cap Standoff Distance: 4.0 cm

Scan Depth from Probe Cap: 2.0/4.0 cm

Frame Rate: 24 frames/second

Line Density: 129 lines/frame

Focal Length: 0.5 cm from cap

Focal Zone: 0.0 to 1.5 cm from cap

7.5 MHz Probe

Ultrasonic Frequency: 7.5 MHz

Sector Angle: 26°

Crystal to Cap Standoff Distance: 4.0 cm

Scan Depth from Probe Cap: 2.0/4.0 cm

Frame Rate: 24 frames/second

Line Density: 129 lines/frame

Focal Length: 2.0 cm from cap

Focal Zone: 1.0 to 4.0 cm from cap

10.3 Site~Rite* IV Power Source Specifications

DC Battery Pack Specifications

Dimensions: 5.0" (12.7 cm) W x 4.25" (10.8 cm) H x 1.75" (4.5 cm) L

Weight: 1.9 lbs. (0.86 kg)

Battery Type: Nickel-Metal Hydride

Output Voltage: 14.4 VDC

Duration of Site~Rite IV Operation when fully charged: 2 hours

AC Adapter Specifications

Dimensions: 5.0" (12.7 cm) W x 4.25" (10.8 cm) H x 1.75" (4.5 cm) L

Weight: 1.4 lbs. (0.64 kg)

Input Voltage: 100 - 240 VAC, 50 - 60 Hz, 1.2 amp

Output Voltage: 15 VDC

Charge~Rite Battery Charger Specifications

Dimensions: 8.0" (20.3 cm) W x 4.7" (11.9 cm) H x 6.4" (16.3 cm) L

Weight: 3.2 lbs. (1.5 kg)

Approximate Time for 85% Battery Recharge: 2.5 hours

Power Source: 90 - 264 VAC, 47 - 63 Hz, 1.0 amp

Site~Rite Mini Battery Charger Specification

Dimensions: 2.2" (55mm) W x 1.7" (43mm) H x 3.2" (80mm) L

Weight: 0.450 Lbs. (0.204 kg)

Approximate Time for 85% Battery Recharge: 2.5 hours

Power Source: 100 - 250 VAC, 50 - 60 Hz, 1.0 amp

IEC 60601- 1: Class II, Continuous Operation, Not Category AP or APG Equipment, Not protected against ingress of water.

US Part Number: NX1210MU6DBNN

EU Part Number: NX1210ME6DBNN

10.4 Site~Rite* IV Ultrasound System Standards Information

The Site-Rite IV Ultrasound System is designed to comply with applicable sections of the following International Standards:

- IEC 60601- 1

- IEC 60601- 2- 37

- IEC 68- 2- 13
- IEC 60601- 1- 2

- IEC 68- 2- 1
- EN 55011: 2000 Class A

- IEC 68- 2- 2

NEMA Standard Publications “Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment” UD- 2

NEMA Standard Publications “Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment” UD- 3

10.5 Site~Rite* IV Ultrasound System Disposal Information

To return the Site-Rite 5 System for end of life recycling, please contact your nearest Bard sales or distributor office in the country of purchase.

Warning: Always properly dispose of dead battery packs in accordance with local regulations. Improper disposal may present an environmental hazard.

10.6 Site~Rite* IV Probe Acoustic Output Specifications

Caution: Any given Ultrasound Procedure should be performed using the principle of ALARA (As Low As Reasonably Achievable). The Site-Rite IV System holds the acoustic output of the device constant. The licensed medical practitioner should limit the time of patient exposure to ultrasonic radiation using the principle of ALARA.

Description of Probe	Operating Mode	I _{spta} X (X denotes statistically determined maximum)	FDA I _{spta} ·3 Published Values	MI X (X denotes statistically determined maximum)	FDA MI Published Values
7.5MHz Probe	B	0.31mW/cm ²	Peripheral Vessel < 720mW/cm ²	0.18	Peripheral Vessel < 1.9
9.0MHz Probe	B	1.22mW/cm ²	Cardiac < 430mW/cm ² Fetal Imaging and other* < 94mW/cm ²	0.38	Cardiac < 1.9 Fetal Imaging and other* < 1.9

*Abdominal, Intraoperative, Pediatric, Small Organ (breast, thyroid, testes, etc.), Neonatal Cephalic, Adult Cephalic.

All measurements were conducted in accordance with the measurement procedures of the NEMA Standard Publications UD-2 [1] and UD-3 [2], and following the calibration procedures given in Appendices B, C, D and E of the 1985 FDA 510(k) Guide, and Part A, Sections III-IV, and Appendices A, B, C and D of the 1989 FDA 510(k) Guide, and the Track 1 and Track 3 reporting requirements of the September 30, 1997 Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers[3].

Bard and Site~Rite are registered trademarks of C.R. Bard, Inc., or an affiliate.

Charge~Rite is a trademark of C.R. Bard, Inc., or an affiliate.

CIDEX is a registered trademark of Johnson and Johnson Corporation.

Micro™ Fuse is a trademark of Littelfuse, Inc.

Components of the Site~Rite IV Ultrasound System are covered by U.S. Patent No. 5,235,987.

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SITE~RITE IV* Ultrasound System WITH RESPECT TO ELECTRIC SHOCK, FIRE, MECHANICAL AND OTHER SPECIFIED HAZARDS ONLY IN ACCORDANCE WITH CAN/CSA C22.2 NO. 601.1 <50TK>

Warning

This product is regulated by the Federal Food and Drug Administration in the United States of America, as well as other agencies throughout the world. This product is ISO certified and CE approved. Therefore, any modification to the product, except those made by the manufacturer, is strictly prohibited by law.

Federal (U.S.A.) law restricts this device to sale by or on the order of physician.

This product should only be operated by qualified medical personnel.

Precaution

Any given Ultrasound Procedure should be performed using the principle of ALARA (As Low As Reasonably Achievable). The Site~Rite IV System holds the acoustic output of the device constant. The licensed medical practitioner should limit the time of patient exposure to ultrasonic radiation using the principle of ALARA.

Site~Rite* IV Ultrasound System Manufactured by:

Bard Access Systems, Inc.

Salt Lake City, UT 84116

U.S.A.

(801) 595-0700

Customer Service: (800) 545-0890

Technical/Clinical Information: (800) 443-3385

Fax: (801) 595-4948

www.bardaccess.com

Site~Rite* Mini Battery Charger Manufactured by:

EGSTON Eggenburger System Elektronik

Grafenberger Straße 37

3730 Eggenburg

AUSTRIA

Phone: +43(2984)2226-0

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WWW: <http://www.egston.com/>

Site~Rite Needle Guides Distributed by:*

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